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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,693	05/26/2000	Masaya Yamanouchi	20-4710P	9841

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	17

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,693	YAMANOUCHI ET AL.	
	Examin r	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,9,14-19 and 21-26* is/are pending in the application.

4a) Of the above claim(s) *14,15,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,6,9,16-19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2,4,6,9,14-19 and 21-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Restriction Requirement mailed 07 January 2003 is acknowledged (paper #16 filed 2/6/03). Therein Applicant has elected Group I, claims 16, 2, 4, 6, 9, 17-19, and 21-24 (drawn to a method for diagnosis or prognosis of a kidney disease) with traverse. Applicant does not traverse the Restriction Requirement on the grounds of lack of patentable distinctness. The traversal on the ground(s) "that the instant international or national stage application containing different categories (three distinct methods of Groups I, III, and IV) all employ the same special technical feature (liver fatty acid binding protein) and as such should be considered to have unity of invention. This argument is not found convincing, because under 37 CFR 1.475 (d) If multiple products, processes of manufacture or uses are claimed, [different categories] the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See PCT Article 17(3)(a) and § 1.476(C). Accordingly the claims were not rejoined.

The Restriction Requirement is still deemed proper and is therefore made **FINAL.**

2. Currently, claims 2, 4, 6, 9, 14-19, and 21-26 are subject to Restriction and Election Requirement. Claims 14, 15, 25, and 26 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 2, 4, 6, 9, 16-19, and 21-24 are currently pending and under examination.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 has cited the references they have not been considered.

4. The information disclosure statements filed 10/3/02-Paper#14 has been considered as to the merits prior to final action.

Applicant notes that the references cited in the specification not submitted in an Information Disclosure Statement(IDS) are merely background and not intended for disclosure to the USPTO. Therein the objection is withdrawn.

OBJECTIONS MAINTAINED

Drawings

5. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Response to Arguments

6. Applicant is required to file a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i). The objection is maintained.

REJECTIONS WITHDRAWN

7. Applicant has corrected the claim objections, claim rejections under the second paragraph of 35 U.S.C. 112, and claim rejections under the first paragraph of 35 U.S.C. 112 of record in paper #12 mailed 6/3/02. The claims have been amended, cancelled, or argued to obviate the objections and/or rejections. Accordingly they are withdrawn.

Claim Rejections

8. With respect to the claim rejections under 35 U.S.C. 102 and 35 U.S.C. 103, Applicant's argument that the liver-type binding protein taught by Olson et al. is specific to male rats, while the instant invention is directed to human FABP. This argument has been found convincing. The following rejections are withdrawn:

I. Claims 2, 4, 6, 16, 17, 18, 20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (Toxicology and Applied Pharmacology, Vol.102., 1990, pages 524-536) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290).

II. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (Toxicology and Applied Pharmacology, Vol.102., 1990, pages 524-536) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Kimura et al. (Journal of Biological Chemistry, 3/25/91, Vol.266., No.9., pages 5963-5972).

III. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (Toxicology and Applied Pharmacology, Vol.102., 1990, pages 524-536) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Galaske et al. (Pflugers Archives European Journal of Physiology, 1978, 375,3, 269-277-ABSTRACT ONLY).

IV. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (Toxicology and Applied Pharmacology, Vol.102, 1990, pages 524-536) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Zuk et al. (U.S.Patent #4,281,061).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 2, 4, 6, 16, 17, 18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290).

Gorski et al. disclose a comparative study evaluating the increased concentration of fatty acid binding protein (FABP) concentrations in plasma samples of patients with chronic renal failure. Plasma FABP concentration was measured by a sensitive noncompetitive sandwich ELISA. PAGE 194 2nd column. Plasma FABP concentration is shown to markedly increase in patients with chronic renal failure. Page 194, 3rd column. The findings suggest that the kidney plays a dominant role in the clearance of plasma FABP. Page 194 3rd column.

Gorski et al. differ from the instant invention in not specifically teaching the detection of liver-type fatty acid binding protein.

However, Maatman et al. identified the liver-type fatty acid binding protein utilized in the instant invention. Page 285, 1st column. This is supported by Applicants arguments (page 24 of the response filed 9/14/01 in paper #7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the liver-type fatty acid binding protein as taught by Maatmann et al., to detect the specific kidney diseases relating to FABP in the method of Gorski et al. because Maatman et al. taught that "the liver-type FABP binds various ligands and may be involved in the renal excretion of exogenous and endogenous metabolites. The liver-type FABP also binds some drugs and may in this way prevent nephrotxicity". Page 289, 2nd column 1st paragraph.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Kimura et al. (Journal of Biological Chemistry, 3/25/91, Vol.266., No.9., pages 5963-5972).

See discussion of Gorski et al. in view of Maatman et al. as set forth above.

Gorski et al. differ from the instant invention in failing to teach that the liver-type FABP is found in the proximal tubule of the kidney and does not cross-react with a heart muscle-type fatty acid binding protein.

However, these characteristics of α_{2U}-globulin were already known in the prior art. Specifically Kimura et al. disclose that fatty acid-binding proteins found in the kidney could be distinguished according to their primary structure and histologic distribution. Two specific FABPs weighing 14 and 15.5 kDa were found in male rat kidney cytosol. The 14 kDa compound was identified as heart FABP and localized in the cytoplasm of the epithelia of the kidney distal tubules. The 15.5 kDa compound was identified as a proteolytically modified form of α_{2U}-globulin (alpha 2u-globulin) and localized in the endosomes or lysosomes of kidney proximal tubules.

Gorski et al. in view of Maatman et al. and Kimura et al. are all analogous art because they are from the same field of endeavor, both inventions teach methods involving FABP detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibody which would not cross-react with a muscle-type fatty acid binding protein as taught by Kimura et al., to detect the specific kidney FABP in the method of Gorski et al. in view of Maatman et al. because such antibodies as taught by Kimura et al. are well known in the art.

A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such antibody assays, because Kimura et al. had already taught that the kidney contained two different types of fatty acid binding proteins, one designated the heart-FABP and the other designated the kidney-FABP. (page 5964, Results).

One having ordinary skill in the art would have been motivated to distinguish between the two types by employing an antibody that would not cross react with the other type (heart-FABP/kidney distal tubules) in order to receive an accurate, more precise measure of the concentration of the FABP of interest (in this case kidney-FABP/ kidney proximal tubules).

III. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Galaske et al. (Pflugers Archives European Journal of Physiology, 1978, 375,3, 269-277-ABSTRACT ONLY).

Please see previous discussions of Gorski et al. in view of Maatman et al.

Gorski et al. in view of Maatman et al. differ from the instant invention in not teaching a detection system involving a chronic renal disease (anti-GMB-nephritis model) further monitoring specimen collection at various intervals.

Galaske et al. disclosed the glomerular filtration and tubular uptake of plasma proteins in the acute heterologus phase of an anti-GMB nephritis model. Injections of anti-glomerular-basement membrane serum (anti-GMB-serum) were evaluated in tubular reabsorption and tubular flow at various times. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a anti-GMB nephritis model as taught by Galaske et al., to detect kidney diseases via proteins in the method of Gorski et al. in view of Maatman et al. because Galaske et al. disclose that such models existed allowing for protein detection in plasma and urine.

One of ordinary skill in the art would have been motivated to do this in order to detect renal disorders at the onset and follow the disease progression/regression.

IV. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and further in view of Zuk et al. (U.S.Patent #4,281,061).

The teachings of over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) are set forth above. Although the reference teaches reagents for examining kidney disease, the references fail to teach the assay as a kit.

However, Zuk et al. (4,281,061) teach that "as a matter of convenience the reagents [of an immunoassay} can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the kidney disease detection assay as taught by over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

Response to Arguments

10. Applicant contends that the reference of Olson et al. is concerned with rat hyaline droplet nephropathy, which is specific to male rats. Further it was noted that this disorder was caused by a globulin not found in humans. This argument was carefully considered and found persuasive. The reference of Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) was added to correct the cited deficiencies.

11. For reasons aforementioned, no claims are allowed.

Remarks

12. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Nagasawa (Japanese Med. Res. Found. Publ. 1979, 7 (Glomerulonephritis), pages 39-51)- ABSTRACT ONLY teach that the binding distribution of Con A is similar anti-nephritogenic glycoprotein antibody.

13. New grounds of rejection were presented in the Office Action. It is therefore made NON- **FINAL.** Examiner apologizes for any inconvenience this may cause Applicant.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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